

MARCH 2018 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>BORTEZOMIB</p> <p>Injection 1 mg in 1 vial Injection 3 mg in 1 vial Injection 3.5 mg in 1 vial</p> <p>Velcade®</p> <p>Janssen-Cilag Pty Ltd</p> <p>(Departmental discussion paper)</p>	<p>Multiple myeloma</p>	<p>The Department sought PBAC approval to streamline the current written Authorities for bortezomib for all its multiple myeloma (MM) PBS restrictions.</p>	<p>The PBAC supported a proposal from the Department to streamline the current written Authorities for bortezomib for all its multiple myeloma (MM) PBS restrictions. The PBAC considered the change should be subject to monitoring of use for inappropriate increases in use outside the restrictions. In making this decision, the PBAC considered this to be the first step in providing easier access to a proven effective MM therapy, noting there will be an upcoming stakeholder meeting for MM which will provide the PBAC with input from key stakeholders about the discrepancies between current PBS listings and treatment guidelines, and the barriers to availability of combination therapies on the PBS.</p>

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<p>BUDESONIDE WITH EFORMOTEROL</p> <p>Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with eformoterol fumarate dihydrate 6 micrograms per dose, 120 doses</p> <p>Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with eformoterol fumarate dihydrate 12 micrograms per dose, 120 doses</p> <p>DuoResp® Spiromax®</p> <p>Teva Pharma Australia Pty Limited</p> <p>Change to listing (Other Submission)</p>	<p>Asthma and chronic obstructive pulmonary disease (COPD)</p>	<p>The Minister requested the PBAC to review the advice previously provided regarding the brand equivalence ('a' flag) of DuoResp Spiromax to Symbicort brands.</p>	<p>The PBAC re-affirmed its November 2017 PBAC meeting recommendation to list a new brand of budesonide with formoterol (DuoResp® Spiromax®) sponsored by Teva Pharma Australia for the treatment of asthma and COPD. In addition, the PBAC re-affirmed its advice to the Minister that DuoResp® Spiromax® can be 'a' flagged against the corresponding strengths of the Symbicort® Turbuhaler® sponsored by AstraZeneca.</p> <p>The PBAC noted that DuoResp Spiromax, if PBS listed by the Minister as recommended by the PBAC, would be available in a different device to Symbicort Turbuhaler, would be indicated for use in patients 18 years of age and over, and would not be available in a 100/6 strength. The PBAC considered that the data available supporting the clinical non-inferiority of DuoResp Spiromax to Symbicort Turbuhaler, the ease of use of the DuoResp Spiromax device and the small proportion of use of the 100/6 strength of Symbicort Turbuhaler, together with the clear specification of the different age restrictions in the PBS Schedule, supported making DuoResp Spiromax substitutable for equivalent strengths of Symbicort Turbuhaler.</p> <p>The PBAC noted the ability for prescribers and pharmacists to substitute generic brands for originator brands is an important part of encouraging use of generics in the marketplace and adds to the sustainability of the PBS.</p> <p>The PBAC noted for any individual prescription, a prescriber may choose to not permit brand substitution by indicating 'substitution not permitted' on the prescription. Likewise, when substitution is permitted, a patient may nominate which 'a' flagged brand they wish to receive from the pharmacist, except when State or Territory Law prohibits substitution (e.g. for Schedule 8 drugs of dependence). The substitution process allows for patient and prescriber choice and is not automatic.</p> <p>The PBAC re-iterated that it considered that any differences in DuoResp Spiromax and Symbicort Turbuhaler devices could be safely managed by health care professionals in the course of regular patient education and counselling that is provided on the use of devices.</p> <p>The PBAC considered that the training of health care professionals and consumers outlined by Teva in its submissions to the PBAC demonstrated the commitment of the sponsor to ensuring appropriate training and education is provided. The PBAC reflected on the National Medicines Policy which requires a shared responsibility across health care professionals, industry and the reimbursement agency to ensure appropriate Quality Use of Medicines measures are taken.</p>

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Biosimilar medicines (PBAC matter)	Biosimilar medicines (multiple uses)	Considering brand equivalence/substitution for biosimilar medicines	<p>The PBAC advised that the following revised considerations will be used to inform advice regarding brand equivalence ('a' flagging) of biosimilars with the reference brand:</p> <ul style="list-style-type: none"> • The Therapeutic Goods Administration (TGA) has determined that the product is a biosimilar of the reference medicine as evidenced by ARTG registration documentation; • Availability of supportive data relating to the effects of switching between the reference product and the biosimilar product/s; and • Practical considerations relating to substitution by the pharmacist at the point of dispensing. This includes strength of formulation, number of units per pack and maximum quantities between the brands, which may make substitution at the pharmacy level difficult from a practical perspective. <p>The PBAC considered that the information regarding biosimilars has evolved significantly over the last 3 years. The PBAC acknowledged that according to the biosimilar regulatory pathway guidelines, TGA cannot make a determination of biosimilarity if concerning evidence exists relating to differences in efficacy or safety between the biosimilar and the reference medicines. The PBAC noted that the TGA determination of biosimilarity relies on the totality of the evidence supporting the biosimilar.</p> <p>The PBAC was also of the view that based on the revised considerations, TGA-PBAC parallel processing should not be made available for proposed biosimilar medicines (i.e. yet to be determined by the TGA). The PBAC noted that the parallel process arrangements were originally established within an agreement with Medicines Australia, who would be consulted on the implementation of these changes to the parallel processing arrangements.</p>

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<p>Matters relating to PBS Review (DUSC Analysis)</p>	<p>Prescriber bag medicines Drugs used for emergencies</p>	<p>To review currently listed drugs and consider requests to add new drugs and prescriber types.</p>	<p>The PBAC considered a report reviewing the utilisation of the Prescriber Bag Section (also referred to as the Emergency Drug Supply list). The PBAC had no specific concerns about use of medicines on this list by medical practitioners and nurse practitioners.</p> <p>PBAC re-iterated the purpose of the Prescriber Bag is to reduce presentations at hospital emergency departments or urgent treatment immediately prior to or during transport to a hospital emergency department.</p> <p>The PBAC considered correspondence from the Australian College of Midwives requesting access to the Prescriber Bag. The PBAC requested that the Department seek further clarification in relation to the request.</p> <p>The PBAC noted that correspondence with pharmaceutical companies in relation to requested changes from earlier reviews of the Prescriber Bag are in train.</p>

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<p>Matters relating to PBS review:</p> <p>Salbutamol Terbutaline Ipratropium Beclomethasone Fluticasone Budesonide Ciclesonide Sodium cromoglycate Nedocromil sodium Montelukast Salmeterol Eformoterol Fluticasone with Salmeterol Fluticasone with Eformoterol Fluticasone with Vilanterol Budesonide with Eformoterol Oral glucocorticoids, plain</p> <p>(All listed brands)</p> <p>(Evaluation of the 2014 post-market review of PBS medicines used to treat asthma in children)</p>	<p>Asthma</p>	<p>To consider the findings from the evaluation of the 2014 Post market review of PBS medicines used to treat asthma in children.</p>	<p>The PBAC considered the evaluation report conducted three years following the 2014 Post-market review of Pharmaceutical Benefits Scheme medicines used to treat asthma in children. The PBAC accepted the 2017 evaluation report, which included more recent utilisation and clinical evidence.</p> <p>The PBAC noted that while there was some reduction in the percentage of children initiating treatment with a fixed dose combination (FDC) of inhaled corticosteroid (ICS)/Long-acting β adrenoceptor agonists (LABA), the proportion of use outside clinical guidelines continued to be unacceptably high. They also considered that the systematic review of comparative clinical effectiveness showed there was no apparent clinical benefit associated with the use of ICS/LABA versus ICS alone in children.</p> <p>The PBAC recommended that all ICS/LABA listings be changed to Authority Required (Streamlined) to encourage prescribers to consider first line treatment with ICS alone. Noting that the report also confirmed that 95% of ICS/LABA prescriptions are written by General Practitioners, the PBAC recommended that the evaluation report be forwarded to the Royal Australian College of General Practitioners, the Australian College of Rural and Remote Medicine and NPS MedicineWise to inform educational programs for General Practitioners on the rationale for the restriction changes.</p>

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<p>Matters relating to PBS review:</p> <p>FLUCONAZOLE Diflucan®, Pfizer Australia Pty Ltd; Dizole®, Fluconazole Alphapharm®, Alphapharm Pty Ltd; Fluconazole-Sandoz®, Sandoz Pty Ltd; Ozole®, Sun Pharma ANZ Pty Ltd; APO-fluconazole®, Apotex Pty Ltd; Fluzole®, Arrow Pharma Pty Ltd</p> <p>ITRACONAZOLE Lozanoc®, Mayne Pharma International Pty Ltd; Sporanox®, Janssen-Cilag Pty Ltd; APO-itraconazole®, Apotex Pty Ltd; Itranox®, Arrow Pharma Pty Ltd; Itracap®, Alphapharm Pty Ltd;</p> <p>(DUSC Analysis)</p>	<p>Antifungals</p>	<p>To consider options to address the increasing use of PBS subsidised fluconazole and itraconazole after they changed from Authority Required (STREAMLINED) to Restricted Benefit listings.</p>	<p>The PBAC noted the increase in the use of fluconazole and itraconazole following the change in the restriction level for these listings to a Restricted Benefit. The PBAC considered that this was likely to have been mostly driven by recommendations in therapeutic guidelines for the use of these drugs to treat acute and chronic candidal vulvovaginitis.</p> <p>The PBAC recommended reinstating the Authority Required (STREAMLINED) listings for fluconazole and itraconazole. The PBAC considered the streamlined authority was necessary because of the potential for these medicines to be used in indications where it has not determined the comparative effectiveness and cost. The PBAC also recommended the addition of a note to the restrictions for oral fluconazole and itraconazole stating that they are not for use in vulvovaginal candida infections.</p> <p>The PBAC considered that the provision of compliance and education activities for prescribers about the appropriate use of PBS listed antifungals should be explored.</p>

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<p>Matters relating to PBS review:</p> <p>Omeprazole Pantoprazole Lansoprazole Rabeprazole Esomeprazole Esomeprazole, clarithromycin & amoxicillin Omeprazole, amoxicillin & clarithromycin (delisted in 2014)</p> <p>(All current and previously listed brands including generic versions)</p> <p>(Post market review report)</p>	<p>Gastro-oesophageal reflux disorders (GORD)</p>	<p>To consider a drug utilisation review of use of PBS listed Proton Pump Inhibitor medicines and review DUSC's consideration of the findings.</p>	<p>The PBAC considered the advice from DUSC on the utilisation patterns of Proton Pump Inhibitors (PPIs) used in the management of gastrointestinal acid related disorders. The PBAC agreed that in comparison to the clinical guidelines and considering the prevalence of Gastro-oesophageal reflux disorders (GORD), high dose PPIs appear to be overprescribed in Australia, for excessively long periods of time, particularly amongst older people. The PBAC considered that this is not in the best interests of patients and is not without safety concerns. The PBAC were particularly concerned by the large number of high and highest dose prescriptions dispensed (95%) relative to low dose PPIs (5%) across 2013-2016. The PBAC noted that this pattern of utilisation is contributing to the high PBS expenditure on PPIs. The PBAC agreed that changes to the restriction levels and/or number of repeats should be reconsidered along with revision of the wording and terminology of all PPI PBS restrictions at a subsequent meeting.</p>
<p>Matters relating to post market review of ezetimibe:</p> <p>FENOFIBRATE Tablet 48 mg, 145 mg Lipidil®, Mylan Health Pty Ltd</p> <p>GEMFIBROZIL Tablet 600 mg Ausgem®, Arrow Pharma Pty Ltd; Lipigem®, Alphapharm Pty Ltd</p> <p>AMPLODIPINE WITH ATORVASTATIN (Various strengths and multiple brands)</p>	<p>High cholesterol</p>	<p>To consider the proposed changes to PBS restrictions following the post market review of ezetimibe.</p>	<p>At its July 2017 meeting, the PBAC considered the Post Market Review of ezetimibe, and recommended that the requirement to meet the clinical criteria set out in the General Statement for Lipid-Lowering Drugs (GSLLD) be removed from the Pharmaceutical Benefit Schedule (PBS) and that PBS listed statins be changed to unrestricted benefits. Prior to implementation, the department sought the PBAC's advice on the flow on effect of this change to fenofibrate, gemfibrozil and the amlodipine with atorvastatin fixed dose combination (FDC) restrictions.</p> <p>The PBAC recommended that the Restricted Benefit for fenofibrate (48 mg, 60 tablets, 145 mg, 30 tablets, maximum repeats 5) and gemfibrozil tablets (600 mg, 60 tablets, maximum repeats 5) be changed to unrestricted benefits, consistent with the derestriction of statins. The PBAC considered that the clinical place of fenofibrate and gemfibrozil was well established and derestriction was unlikely to result in inappropriate prescribing or changes in prescribing patterns. However, the PBAC advised that utilisation should be monitored.</p>

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(Post market review report)			<p>The PBAC recommended the 12 month repeat prescription restrictions for gemfibrozil and fenofibrate (maximum repeats 11) remain Restricted Benefit with the following PBS indication: “patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements”, for consistency with other medicines including statins available under this measure.</p> <p>The PBAC recommended that the Restricted Benefit for amlodipine with atorvastatin FDC be changed to unrestricted benefit for all indications. Both monotherapies are PBS-listed as unrestricted benefits. The PBAC noted that the FDC has been PBS listed for some time with relatively stable utilisation and considered that the majority of prescribers are familiar with this formulation. The PBAC therefore considered that the risks associated with moving FDC amlodipine and atorvastatin to an unrestricted benefit listing were low.</p>
<p>QUETIAPINE</p> <p>Tablet 25 mg</p> <p>(APO-Quetiapine®, Apotex Pty Ltd); (Chemmart Quetiapine®, Apotex Pty Ltd); (Delucon®, Aurobindo Pharma Australia Pty Ltd); (Kaptan®, Eris Pharmaceuticals Australia Pty Ltd); (Pharmacor Quetiapine®, Pharmacor Pty Ltd); (Quetia®, Arrow Pharma Pty Ltd); (Quetiaccord®, Accord Healthcare Pty Ltd); (Quetiapine Actavis®, Actavis</p>	<p>Schizophrenia, acute mania and bipolar I disorder</p>	<p>The Royal Australian and New Zealand College of Psychiatrists (RANZCP) requested that the 25 mg form of the drug quetiapine be made available for maintenance therapy with 5 repeats.</p>	<p>PBAC recommended that the current listing for the 25 mg strength quetiapine tablets be changed to allow for up to 5 repeats via Authority Required prescription for maintenance therapy for treatment of acute mania, bipolar 1 disorder and the treatment of schizophrenia.</p>

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<p>Australia Pty Ltd); (Quetiapine AN®, Amneal Pharma Australia Pty Ltd); (Quetiapine GH®, Generic Health Pty Ltd); (Quetiapine Pfizer®, Scentia Pharmaceuticals Pty Ltd); (Quetiapine RBX®, Ranbaxy Australia Pty Ltd); (Quetiapine Sandoz®, Sandoz Pty Ltd); (Quetiapine-DRLA®, Dr Reddy's Laboratories Australia Pty Ltd); (Quetiapine-GA®, Actavis Australia Pty Ltd); (Seronia®, Arrow Pharma Pty Ltd); (Seroquel®, AstraZeneca Pty Ltd); (Syquet®, Accord Healthcare Pty Ltd); (Terry White Chemists Quetiapine®, Apotex Pty Ltd) Change to listing (Correspondence)</p>			